

CLAIMS

1. An intravitreal injectable solution for the treatment of vitreal hemorrhages, which comprises: a pharmaceutically effective quantity of an active ingredient; and a pharmaceutically acceptable quantity of a carrier solution; wherein the active ingredient is mannitol and the carrier solution comprises 10.20% in weight of polyoxyl stearate 40; 0.15% in weight of edetate disodium, dihydrate; 1.03% in weight of sodium chloride; 0.14% in weight of boric acid; 0.32% in weight of sorbic acid; 0.06% in weight of sodium bisulfate and 88.00% in weight of distilled water.
2. The intravitreal injectable solution, according to claim 1, characterized in that said carrier solution is Sophisen®.
3. The intravitreal injectable solution, according to claim 1, characterized in that mannitol is present in a concentration that encourages the reabsorption of the vitreal hemorrhage.
4. The intravitreal injectable solution, according to claim 3, characterized in that the mannitol is present in the solution in a percentage of 5% to 30% in weight.
5. The intravitreal injectable solution, according to claim 1, characterized in that the Sophisen® is present in the solution in a percentage of 0.05% to 20% in weight.
6. The intravitreal injectable solution, according to claim 1, characterized in that the pH of the solution is approximately 7.2.
7. The intravitreal injectable solution, according to claim 1, characterized in that the solution has an osmolarity of approximately 1400 mOsm/kg.
8. A method for the treatment of vitreal hemorrhages comprising the steps of: applying at least one injection of an ophthalmic solution including mannitol, into the vitreal humor of an eye with a

hemorrhage resulting from a lesion or disease.

9. The method according to claim 8, characterized by applying at least one therapeutically effective dose of the injectable solution of claim 1, into the vitreous humor of a patient diagnosed with vitreous hemorrhage.
10. A method for the clarification of vitreous hemorrhages comprising the injection, into the vitreous body of the eye of a patient, of an ophthalmic solution, such as the one claimed in claim 1.
11. The method of the preceding claim, which is aimed at avoiding vitrectomy surgery in patients with vitreous hemorrhage, by the application of at least one intraocular injection of an ophthalmic solution formulated for the reabsorption of the hemorrhage.
12. The new use of mannitol as active ingredient of a solution that is injectable into the vitreous body of the eye for the treatment of vitreous hemorrhages.
13. A method for the preparation of an ophthalmic solution for an intravitreal injection for the treatment of vitreous hemorrhages, characterized by the following steps: pouring into a stainless steel recipient 800 ml of injectable water at a temperature of $40^{\circ}\text{C} \pm 2^{\circ}\text{C}$; beginning the agitation at $200 \text{ rpm} \pm 50 \text{ rpm}$ and keeping it constant throughout the entire preparation process; slowly adding 200 g of mannitol; cooling the solution until it reaches a temperature of less than 35°C ; adding 1.0 g of sodium phosphate monobasic monohydrate; adding 5.1 g of sodium phosphate dibasic anhydrous; adding 1.0 ml of Sophisen[®]; bringing it to a volume of 1 liter with injectable water; and agitating at $200 \text{ rpm} \pm 50 \text{ rpm}$ until complete homogeneity is obtained.
14. An intravitreal injectable solution for the treatment of vitreous hemorrhages comprising: a pharmaceutically effective quantity of mannitol: 0.01% to 5% in weight of sodium phosphate monobasic

monohydrate; 0.01% to 5% in weight of sodium phosphate dibasic anhydrous and 100 ml of injectable water.

15. The intravitreal injectable solution of claim 14, in which the mannitol is present in a percentage of 5% to 30% in weight of the solution.

5 16. The intravitreal injectable solution of claim 14, which further includes 0.05% to 20% in weight of a carrier solution.

17. The intravitreal injectable solution of claim 14, wherein the carrier solution is Sophisen[®].

ABSTRACT

The present invention relates to an ophthalmic solution for the clarification of vitreous hemorrhages. More specifically, it relates to a
5 pharmaceutically acceptable intraocular injectable solution, for the treatment of vitreous hemorrhages, whereby the reabsorption of such hemorrhage is encouraged. It enables the clarification of the vitreous hemorrhage in a significantly short period of time to allow for the timely diagnosis of the lesion and the repair of the damage the hemorrhage has
10 caused to the vitreous body. The ophthalmic solution of the present invention is injected at least once into the vitreous humor of the patient in a therapeutically effective dose to obtain the desired result.